

REMARKS

Claims 1-88 are pending. Claims 1-57 and 72-88 are withdrawn from consideration.

Claims 58-71 stand rejected. Applicants amend claim 58. Accordingly, after entry of this Amendment, claims 58-71 will be pending for examination. Applicants submit that the amendments introduce no new matter and that claims 58-71 are in condition for allowance.

Amendments to the Claims

Applicants amend claim 58 to correct antecedent basis, to remove unnecessary language, and to clarify the purpose of the invention in the non-limiting preamble. Claim 58 also is amended to clarify that the method includes the step of administering a non-metallic composition to skin. Support for a non-metallic composition, i.e., a composition that does not include a metallic biocide, is found in the application as filed at least at page 22, lines 3-9 (where the addition of a metallic biocide to the polycationic antimicrobial material is optional), in Examples 6 and 7 on pages 28 and 29, and in Example 13 on page 35 which includes in Table V, Samples 5002-74-2 and 5002-75-2. Accordingly, Applicants submit that no new matter is introduced by these amendments.

Status of Non-Elected Claims

Applicants note that the Office action indicates that a complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action. Because the Office action is not a final action, Applicants do not cancel the nonelected claims herein.

Claim Rejections Under 35 U.S.C. § 112

Claims 58-70 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office action asserts that in claim 58, the limitation of "the duration of efficacy of a dermal antiseptic formulation" is unclear as to which duration of efficacy of which dermal formulation applicant is claiming as an invention. Applicants submit that the above-quoted

phrase in the preamble is not a limitation but is setting the invention in its proper environment and stating the purpose of the invention. However, without acquiescing to the rejection, Applicants have amended the preamble to recite the non-limiting purpose of the invention: to provide antimicrobial activity on skin. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

The Office action asserts that in line 5 of claim 58, the limitation "the formulation" is unclear as there is insufficient antecedent basis for this limitation. Applicants have deleted this limitation from line 5 thereby rendering this rejection moot.

The Office action asserts that in claim 58, the limitation "thereby enhancing the antimicrobial efficacy of the antiseptic formulation by imparting residual antimicrobial activity" is unclear and that the claim appears incomplete.

With respect to the above-quoted phrase, Applicants have deleted the phrase thereby rendering the questions regarding enhancing activity and "residual antimicrobial activity" moot.

With respect to the claim allegedly being incomplete, Applicants submit that the claim as amended particularly points out and distinctly claims the subject matter which the Applicants regard as the invention. Specifically, Applicants' invention is directed to administering a non-metallic composition to skin, where the non-metallic composition includes a polycationic antimicrobial material and a dermal antiseptic formulation. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claim Rejections Under 35 U.S.C. § 102

Claims 58-71 are rejected under 35 U.S.C. § 102(a) as being anticipated by Sawan et al., PCT International Publication No. WO 98/18330 ('330 publication).

Applicants submit that the '330 publication teaches compositions which include an antimicrobial metal and coating articles with such metal-containing compositions. Claim 58 is directed to administering a non-metallic composition to skin. The '330 publication does not teach, suggest, or motivate administering a non-metallic composition to skin. Accordingly, claim

58 is not anticipated by the '330 publication and Applicants respectfully request withdrawal of this rejection.

Claims 58-61 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,643,181 to Brown (Brown).

Claim 58 is directed to administering a non-metallic composition including a polycationic antimicrobial material and a dermal antiseptic formulation to skin. Applicants submit that Brown does not teach, suggest, or motivate administering a composition including a polycationic antimicrobial material and a dermal antiseptic formulation to skin. Rather, Brown teaches contacting skin with polyhexamethylene biguanide contained within an adhesive, not within a dermal antiseptic formulation. Accordingly, claim 58 is not anticipated by Brown and Applicants respectfully request withdrawal of this rejection.

Claims 58-71 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sawan et al., PCT International Publication No. WO 95/17152 ('152 publication).

The Office action states that the '152 publication discloses antimicrobial coating compositions comprising PHMA-MBDGA-silver coating mixture. Claim 58 is directed to administering a non-metallic composition to skin. The '152 publication does not teach, suggest, or motivate administering a non-metallic composition to skin. Accordingly, claim 58 is not anticipated by the '152 publication and Applicants respectfully request withdrawal of this rejection.

Claims 58-71 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,817,325 to Sawan et al. ('325 patent).

The Office action states that the '325 patent discloses methods of enhancing devices and formulations comprising a PHMB-MBDGA-silver coating on a device or dermal composition. Claim 58 is directed to administering a non-metallic composition to skin. The '325 patent does not teach, suggest, or motivate administering a non-metallic composition to skin. Accordingly,

claim 58 is not anticipated by the '325 patent and Applicants respectfully request withdrawal of this rejection.

In sum, Applicants submit that claim 58 is novel and unobvious over the cited references, either alone or in combination. Because claims 59-71 depend directly or indirectly from claim 58, Applicants also submit that claims 59-71 are patentable over the cited references.

Double Patenting Rejections

Claims 58-71 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 6,180,584, claims 1-6 of U.S. Patent No. 6,030,632, claims 1-9 of U.S. Patent No. 5,869,072, and claims 1-9 of U.S. Patent No. 5,817,325. The Office action states that although the claims are not identical, they are not patentably distinct from each other because each of the cited patents are directed to compositions comprising a biguanide material, a metal material such as silver compounds and a cross linker, and/or methods of using such compositions to improve the antimicrobial activity of an article or secondary formulation.

Claim 58 as amended is a method for providing antimicrobial activity on skin including administering a non-metallic composition to skin. The claimed compositions and methods of the above-cited patents include a metal biocide. Accordingly, Applicants submit that claim 58, as well as claims 59-71 which depend from claim 58, are patentably distinct from the cited claims. Therefore, Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

Based on the above amendments and remarks, Applicants respectfully submit that pending claims 58-71 are in condition for allowance and request entry as such. If the Examiner

Amendment and Response
U.S. Serial No. 09/392,842
Page 7 of 8

believes that a conversation with Applicant's attorney would be helpful in expediting prosecution of this application, the Examiner is invited to contact the undersigned.

Respectfully submitted,



Michael H. Brodowski
Registration No. 41,640

Dated: October 10, 2001
TESTA, HURWITZ & THIBEAULT, LLP
High Street Tower
125 High Street
Boston, MA 02110
Tel: (617) 248-7012
Fax: (617) 248-7100
2190662v1

MARKED UP VERSION OF CLAIMS SHOWING AMENDMENTS

58. (Amended) A method for providing antimicrobial activity on skin [~~enhancing the duration of efficacy of a dermal antiseptic formulation~~], the method comprising the step of:
administering a non-metallic composition to skin, wherein the non-metallic composition comprises [~~mixing~~] a polycationic antimicrobial material and a dermal antiseptic formulation[, such that the antimicrobial material is capable of forming a self-preserving, antimicrobial barrier upon application of the formulation to skin, thereby enhancing the antimicrobial efficacy of the antiseptic formulation by imparting residual antimicrobial activity].